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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,957	02/03/2005	Jonathan S. Stamler	STAM3002 PCT	6780
23364 7590 04/26/2007 BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			EXAMINER HUANG, GIGI GEORGIANA	
			ART UNIT	PAPER NUMBER
			1609	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		04/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/508,957	STAMLER ET AL.	
	Examiner	Art Unit	
	GiGi Huang	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

2. Group I, claims 1-11, drawn to a method of treating a patient in need of GTN (nitroglycerin) therapy with GTN and an mtALDH inhibitor.

Group II, claims 12-21, drawn to a method of increasing or stabilizing blood pressure in a hypotensive patient sensitive to GTN with GTN and mtALDH.

Group III, claims 22-23, drawn to a method of treating a patient with ischemia or congestive heart failure with a nitrite that is *not* GTN.

Group IV, claims 24-34, drawn to a method of treatment comprising administering an organic nitrate and a thiol or a transgene of mtALDH.

Group V, claims 35-41, drawn to a method of treating a patient in need of nitroglycerin therapy with nitroglycerin and a reductant with mitochondrial ALDH activity.

Group VI, claims 42-44, drawn to a method of administering a drug imparting nitric oxide bioactivity and not requiring mtALDH for its metabolism.

Group VII, claims 45-49, drawn to a method of administering a nitro vasodilator which not a substrate for human mtALDH.

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Group VIII, claims 50-51, drawn to a method of treating a patient in need of antianginal and /or preload reducing activity which administering a mitochondria impermeable nitrate or nitrite.

Group IX, claims 52-53, drawn to a method of determining cross-tolerance to nitroglycerin and other drugs.

Group X, claims 54-55, drawn to a method selecting between nitroglycerin other antianginal or preload reducing drugs

Group XI, claims 56-59, drawn to a method for determining the dose of nitrate for a patient.

Group XII, claims 60-68, drawn to a composition for IV administration of nitroglycerin.

3. The inventions listed as Groups I – XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

There is no technical feature linking Groups I – XII.

The scope for each group is different from the next as evidenced by the applicant's own claims.

Group I goes to the use of nitroglycerin in conjunction with a mtALDH inhibitor, while Group III goes to treating a patient with a nitrite not GTN, and Group XII goes to a composition that is nitroglycerin in a carrier.

The special technical feature cannot even be nitroglycerin (which is known) as Group III for example goes to drugs that are not nitroglycerin. The search for each

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group constitutes a different search for each and is therefore not linked by a special technical feature.

Giesselmann (U.S. Patent # 4,481,220) teaches a preparation of nitroglycerin that can be dissolved in water to form an isotonic nitroglycerin solution free of ethanol that can be used for parenteral delivery, which by definition would include IV administration (Abstract, Col. 5, lines 8-18).

Alam et al. (U.S. Patent # 4,879,308) teaches an aqueous solution of nitroglycerin that is suitable for intravenous injection and is free of organic solvents (Abstract, Col. 5, lines, 23-35).

Both preparations listed above are applicable prior art to Group XII but not to some of the groups listed, as they do not share a specific inventive step or novelty.

Therefore, the technical feature linking the inventions of Groups I – XXII does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Accordingly, Groups I – XII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement can be traversed (37 CFR 101.43) and (ii) identification of the claims encompassing the elected invention.

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5. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. The applicant is advised that an election of an invention may be subject to an additional restriction or election of species.

7. Should the applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The inventions are distinct, each from the other because of the following reasons:

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Friday 7:30AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**VICKIE KIM
PRIMARY EXAMINER**

GH

A handwritten signature in black ink, appearing to be 'Vickie Kim', written over a horizontal line.